

§ 416.48

(7) Documentation of properly executed informed patient consent.

(8) Discharge diagnosis.

§ 416.48 Condition for coverage—Pharmaceutical services.

The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services.

(a) *Standard: Administration of drugs.* Drugs must be prepared and administered according to established policies and acceptable standards of practice.

(1) Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.

(2) Blood and blood products must be administered by only physicians or registered nurses.

(3) Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician.

(b) [Reserved]

§ 416.49 Condition for coverage—Laboratory and radiologic services.

(a) *Standard: Laboratory services.* If the ASC performs laboratory services, it must meet the requirements of part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of Part 493 of this chapter.

(b) *Standard: Radiologic services.* (1) Radiologic services may only be provided when integral to procedures offered by the ASC and must meet the requirements specified in § 482.26(b), (c)(2), and (d)(2) of this chapter.

(2) If radiologic services are utilized, the governing body must appoint an individual qualified in accordance with State law and ASC policies who is responsible for assuring all radiologic

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services are provided in accordance with the requirements of this section.

[73 FR 68812, Nov. 18, 2008, as amended at 79 FR 27153, May 12, 2014]

§ 416.50 Condition for coverage—Patient rights.

The ASC must inform the patient or the patient's representative or surrogate of the patient's rights and must protect and promote the exercise of these rights, as set forth in this section. The ASC must also post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients waiting for treatment or by the patient's representative or surrogate, if applicable.

(a) *Standard: Notice of Rights.* An ASC must, prior to the start of the surgical procedure, provide the patient, the patient's representative, or the patient's surrogate with verbal and written notice of the patient's rights in a language and manner that ensures the patient, the representative, or the surrogate understand all of the patient's rights as set forth in this section. The ASC's notice of rights must include the address and telephone number of the State agency to which patients may report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.

(b) *Standard: Disclosure of physician financial interest or ownership.* The ASC must disclose, in accordance with Part 420 of this subchapter, and where applicable, provide a list of physicians who have financial interest or ownership in the ASC facility. Disclosure of information must be in writing.

(c) *Standard: Advance directives.* The ASC must comply with the following requirements:

(1) Provide the patient or, as appropriate, the patient's representative with written information concerning its policies on advance directives, including a description of applicable State health and safety laws and, if requested, official State advance directive forms.

(2) Inform the patient or, as appropriate, the patient's representative of the patient's right to make informed decisions regarding the patient's care.

(3) Document in a prominent part of the patient's current medical record,